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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,104	04/28/2005	Yong Kwee	053466-0401	5920

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EXAMINER	
SANG, HONG	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,104	KWEE ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,12 and 23-31* is/are pending in the application.

4a) Of the above claim(s) *24 and 26-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,12,23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

RE: Kwee et al.

1. Applicant's response filed on 2/4/2009 is acknowledged. Claims 1, 3, 12, and 23-31 are pending. Claims 2, 4-11, and 13-22 have been cancelled. New claims 24-31 was added in applicant's reply filed on 10/23/2008. Claims 24 and 26-31 are withdrawn from further consideration as being drawn to non-elected inventions for the reasons set forth in the previous communication mailed on 12/04/2004. Claims 1, 3, 12, 23 and 25 have been amended.

2. Claims 1, 3, 12, 23 and 25 are under examination.

Objections Withdrawn

3. The objection to claim 14 because it is a duplicate of claim 12 is withdrawn in view of applicant's cancellation of the claim.

Rejections Withdrawn

4. The rejection of claims 1, 3, 12, 14, and 23 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antigen-specific dendritic cell pulsed by an HM1.24 protein or an HM1.24 peptide, does not reasonably provide enablement for a cancer vaccine containing as an active ingredient an antigen-specific dendritic cell pulsed by an HM1.24 protein or an HM1.24 peptide is withdrawn in view of applicant's amendment to the claims to recite "wherein the vaccine is used as a therapeutic".

Rejections Maintained

Claim Rejections - 35 USC § 103

5. The rejection of claims 1, 12, and new claim 25 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27) is maintained.

The response states that Treon neither alone nor together with Ohtomo and Chiriva-Intemati suggests whether or not dendritic cells can be pulsed by idiotypic vaccination using the HM1.24 protein or the HM1.24 peptide, or whether or not the HM1.24 protein or the HM 1.24 peptide can be used for immune therapy. Furthermore, Idiotypic Vaccination and DNA vaccines are different therapies and thus are not fungible. No combination of Treon et al., Ohtomo et al., and Chiriva-Internati et al., teach or suggest whether mature dendritic cells can be obtained by pulsing immature dendritic cells with the HM1.24 protein or the HM1.24 peptide.

Applicant's arguments have been carefully considered but are not persuasive. Treon et al. expressly teach that an alternative strategy of targeted therapy is to generate active specific immunity against the patient's tumor. Treon et al. teach in addition to presenting myeloma associated peptides, the dendritic cells can also be pulsed with whole tumor antigen, naked DNA or whole tumor RNA for treating multiple myeloma (MM) (see page 604, left column). As such treating cancer including myeloma (MM) using dendritic cells pulsed with tumor antigen, or naked DNA was well known in the prior art. Chiriva-Internati et al. teach that pulsing dendritic cells via an adeno-

associated viral vector/HM1.24 recombinant generates rapid, significant cytotoxic T lymphocytes and interferon activity against multiple myeloma and synthetic HM1.24-positive autologous targets (see abstract). Chiriva-Internati et al. teach that HM1.24 may be an effective antigen for targeting MM (see abstract). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one would have been motivated to make dendritic cells pulsed with HM1.24 antigen for treating multiple myeloma because Treon et al. teach in addition to presenting myeloma associated peptides, the dendritic cells can also be pulsed with whole tumor antigen, or naked DNA for treating multiple myeloma (MM) (see page 604, left column), both Treon and Ohtomo teach that HM1.24 is a myeloma specific tumor antigen, and Chiriva-Internati et al. have shown that dendritic cells pulsed with a vector encoding HM1.24 antigen generates rapid, and significant cytotoxic T lymphocytes. One of ordinary skill in the art would have a reasonable expectation of success to make dendritic cells pulsed with HM1.24 antigen for treating MM because Chiriva-Internati et al. have shown that dendritic cells pulsed with a vector encoding HM1.24 antigen generates rapid, and significant cytotoxic T lymphocytes, and the method of making dendritic cells pulsed with a tumor antigen was well known in the art as shown by Treon et al.

It is noted that the instant invention is drawn to an antigen specific dendritic cell pulsed by an HM1.24 protein or HM1.24 peptide, which is not an idiotypic vaccination. The idiotype refers to the segment of an immunoglobulin or antibody molecule that determines its specificity for antigen and is based upon the multiple combinations of

variable (V), diversity (D) and joining (J) exons (see Exhibit A, Cruse et al., Illustrated Dictionary of Immunology, 1995 by CRC press, page 148). The idiotype vaccine refers to antibody preparations that mimic antigens at the molecular level and they induce immunity specific for the antigens they mimic (see Exhibit A).

Regarding the new claim 25, presenting the antigen for helper T-cells is considered as inherent property of dendritic cells.

Because of these reasons, the rejection is deemed proper and is therefore maintained.

6. The rejection of claims 1, 3, 12, 23 and new claim 25 under 35 U.S.C. 103(a) as being unpatentable over Treon et al. (Semin. Oncol. 2000, 27(5): 598-613, IDS) in view of Ohtomo et al. (Biochem. Biophy. Res. Commun., 1999, 258:583-591, IDS), and Chiriva-Internati et al. (Cancer Gene Therapy, 2001, Dec., 8(Suppl 2): S27), further in view of WO 200177362 (Pub. Date: 10/18/2001, IDS), as evidence by Porgador et al. (J. Exp. Med., 1995, 182: 255-260, IDS) is maintained.

Applicants presented the same arguments as the previous 103(a) rejection, these arguments are not persuasive for the same reasons set forth above (see paragraph 5).

Conclusion

7. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643

/Christopher H Yaen/
Primary Examiner, Art Unit 1643